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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/821,719	03/29/2001	Kathleen A. Donovan	07039-260001	4609

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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/821,719

Applicant(s)

DONOVAN ET AL.

Examiner

Myron G. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,8,15,28- 35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,8,15,28- 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to Amendment C, paper11, 10/03/02.

Claims 1, 2, 4, 5, 8, 15, 28, and 28- 35 are pending.

Election/Restrictions

Applicant requests reconsideration of restriction requirement. The requirement remains for reasons of record but is moot now that the claims to the non-elected inventions have been canceled.

Response to Amendment

The arguments have been fully considered and found persuasive in part.

Objections Withdrawn

The objections to claims for multiple dependency and being dependent on themselves is withdrawn because of amendments and cancellation of claims.

REJECTIONS WITHDRAWN

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 1 and 2 were rejected under 35 USC 102. This rejection is moot in light of the amendment.

Claim Rejections - 35 USC § 112

Claims 3, 4 and 15 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is with drawn in light of the amendments and explanation.

Claim Rejections - 35 USC § 103

Claims 1, 2, were rejected under 35 U.S.C. 103(a) as being unpatentable over Carter and Klein (1989 Blood Vol 73, No 2, pages 517- 526).

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 112

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what the correlation is between IL-1 beta and IL-6.

Applicant argues that they do not have to explain why there is a correlation but that it works and that it is based on a positive correlation between IL-1 beta and IL-6.

The argument has been fully considered and not found persuasive.

The claim does not recite positive correlation. It is not clear what the relationship between IL-1 beta and IL-6 is.

New Rejection (Based on Amendment)

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4,5,8, and 30- 35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for IL-6 production, does not reasonably provide enablement for differentiation between various types of myeloma related plasmaproliferative disorders (MRPD). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims are drawn to methods of determining progression from a MRPD condition to MM.

From the data provided in Figures 4, 5A and 5B, it is not clear that the MRPD condition can be differentiated from normal. Figure 4 shows 3 MGUS samples that are similar to background in IL-6 production, less than 2 fold difference, whereas MM is over 10 fold higher production of IL-6. Also, with treatment of antibody, the levels are barely reduced as compared to MM sample. Figure 5A shows 2 MM sample sets and 4 SMM sample sets. One SMM has IL-6 values essentially similar to MM but 3 have IL-6 values

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similar to background as discussed above for Figure 4, which is similar to the normal included in 5B. Figure 5B includes a normal sample set along with other sets.

Because the samples are obtained already knowing MM, MGUS, or SMM state, the assay is not an assay diagnostic of the condition as such. With the samples having low values and not knowing sample error or variability in sample measurements, it is not clear that samples can be differentiated from normals or that samples with small increases are predictive of disease state or just within sample measurement error/variation. Thus it is concluded that it would require too much work to be able to differentiate the samples and know that they are different from normal or increasing and predictive of progression to MM.

Claims 4 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Both claims are drawn to methods that state in the preamble that they quantify IL-6 but the method steps that define the method are drawn to comparing IL-6 levels. It is not clear what the method is intended to be or if the method is complete.

Claim Rejections - 35 USC § 103

Claims 4, 5, 8, 15, 28, and 30- 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (1989 Blood Vol 73, No 2, pages 517- 526).

Applicant argues that the prior art teaches away from a correlation of IL-1B and disease state and that Klein considers IL-1b not relevant to MM or associated conditions.

The arguments have been considered and found persuasive in part. The art cited in the supplemental IDS and used in the argument has also been considered. The claims do not require determining the amount of IL-6 produced in response to IL-1 beta but are drawn to amounts of IL-6. The work of Klein and the assay claimed measure the production of IL-6. Klein (Figure 1) shows a correlation between IL-6 levels and disease state. Klein does not use the direct assay of IL-1B to correlate to MM and neither does the claimed invention. In this case, looking at IL-6, shows a difference between MM and myeloma related plasmaproliferative disorder (MRPD)(Figure 1). In the prior art, individuals are already diagnosed with MRPD or MM. It is noted that Klein in Figure 1 is not able to differentiate healthy individuals from inactive or slightly active myelomas, the claims are drawn to individuals who might progress to multiple myeloma or detecting a change in status/IL-6 level.

Klein does not specifically teach comparison of IL-6 levels to determine change in MM status or likelihood to progress to MM.

It would have been *prima facie* obvious to one of ordinary skill in the art to monitor the IL-6 level to check status or change in status knowing Klein (Figure 1) teaches that IL-6 is different in different disease states.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP


§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 703-308-4521. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4247. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Myron G. Hill
Patent Examiner
February 5, 2003


JAMES HOUSEL 2/10/03
SUPERVISORY PATENT EXAMINER
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